REMARKS

This response is submitted in reply to the Office Action dated May 2, 2006 ("the Action") and the Notice of Noncompliant Amendment dated October 11, 2006. Claims 1-29 and 34-73 are pending in the application. Claims 8, 10-12, 27, 53-55 and 70 are withdrawn from consideration subject to re-entry upon allowance of a generic claim.

Pursuant to the Office Action Election Requirement dated January 25, 2006, Applicant respectfully submits that the claims that are readable on (generic and/or specific to) the elected base material species are Claims 1-7, 9, 13-26, 28, 29, 34-52, 56-69, and 71-73.

Applicant submits that the claims readable on (generic and/or specific to) the fixation configuration shown in Figure 4, include Claims 1-29, 34-71, and 72-73.

The claim set submitted herewith has been revised to note the omitted deletions or non-underlined additions as identified by the Examiner in the Notice of Non-compliant Amendment. Applicant respectfully apologizes for any inconvenience caused by these inadvertent informalities.

I. The Interview

Applicant acknowledges, with appreciation, the time and courtesy extended to Dr. David Ku, the inventor, Dr. Rebeccah Brown, Vice President, Operations, of SpineMedica Corp., the present Assignee of the pending patent application, and Julie H. Richardson, Applicant's representative, in an interview at the USPTO on July 7, 2006. During the interview, Applicant showed the Examiner prototypes of a flexible total disc replacement (TDR) device formed from a freeze-thaw cryogel having aspects or features described in the pending application.

Also during the interview, Applicants discussed various claim terminology that would address the Examiner's concern regarding the written description and clarity objections to certain of the elasticity features in the pending claims. Applicant and the Examiner discussed and agreed that removing the terminology "compressive modulus of elasticity" from certain of the claims that had been used to address the previously objected to recitation of "mechanical elasticity" would obviate the issue with regard to the written description issue of the former

recitation and the clarity of the latter recitation. Applicant has accordingly removed the objected-to elasticity recitations from the pending claim set.

Applicant discussed the objection to "plateless" in the Action, in light of the support for same found in the figures in the instant application, which clearly illustrate the implant both in and out of the body without endplates. Thus, during the interview the term "devoid of endplates" was suggested as more clearly referring to this feature of the invention (*see, e.g.*, Claim 40). Applicant also discussed the word "unitary" as describing a single-piece body and the Examiner suggested that "monolithic" may be appropriate to indicate a single piece construction of an implant. Also, with respect to Claim 8, Applicant pointed to the term "non-constant elasticity or anisotropic elasticity" as described at para. 50 of the corresponding published patent application under Example 3.

Finally, Applicant noted various functional features of embodiments of the invention, such that the implant body can be flexible yet non-articulating, devoid of (rigid) endplates, have a molded unitary or monolithic body (rather than a multi-component articulating assembly that can disengage in the body) and the like.

II. The Written Description Rejections

The Action rejects Claims 1-7, 9, 13-26, 28, 29, 34-52, 56-69 and 71-73 as failing to comply with the written description for the range of the compressive modulus of elasticity claimed in Claim 1 and 48. Applicant has deleted the "compressive modulus of elasticity" feature from at least independent Claims 1, 34, 48 and 63, and requests that this rejection be withdrawn.

The Action rejects the use of the term "about" as the Action opines that it is "believed to not have support." Applicant respectfully disagrees. According to the MPEP, range limitations are acceptable if one of skill in the art would consider them inherently supported by the discussion in the original disclosure. See MPEP 2163.05. Applicant submits that the lack of literal use of the word "about" in certain places in the specification does not limit Applicant's ability to use this term in the claims, as Applicant respectfully submits that one of skill in the art would consider range values close to that recited as inherently supported in the

description rather than an "absolute" threshold value, particularly in light of the use of "about" with respect to other claimed parameter values. Nonetheless, Applicant has canceled this term from at least Claims 3 and 11, but such action is not to be interpreted to limiting any doctrine of equivalents scope of the affected claims, as the term is deleted to advance prosecution and is not deleted to avoid any prior art.

The Action also states that with respect to Claim 8, the term "compressive modulus of elasticity that is not constant" is not mentioned in the original disclosure. However, while not mentioned specifically with the modifier "compressive modulus", it is clearly described for varying elasticity in a physical dimension as described, for example, at para. 50 of the published patent application in Example 3. Accordingly, as discussed at the Interview, this recitation has been amended in Claim 8 to obviate this rejection.

III. Support for Added Claim Limitations

The Action requests that Applicant specifically point out support for every added claim limitation. The following citations are made with respect to the published patent application format.

Claim 2: "compressive strength" sufficient to withstand a compressive load greater than 1 MPa when subjected to loads of the human spine. *See, e.g.*, original Claim 1 and para. 24, lines 3-4.

Claim 3: "ultimate strength in tension and compression" greater than 1 MPa. *See, e.g.*, original Claim 3 and para. 46, line 20 (the end of para. 45 describes the 5 MPa for ultimate strength but does not literally state "tension").

Claim 4: wherein the device is a molded freeze-thaw body formed of a single solid cryogel material, with a mold formulation of polyvinyl alcohol (PVA) powder in an amount of between about 25 to 50% by weight and solvent. *See, e.g.*, para. 45, para. 46 and the figures.

Claim 5: wherein the elastomer has a compressive strength of at least 1.0 MPa. *See, e.g.*, para. 24.

Claim 6: wherein the elastomer has a compressive strength of at least 10 MPa. *See, e.g.*, para. 24.

Claim 7: wherein the device has a compressive modulus of elasticity that is between 0.1 MPa to 10 MPa. *See, e.g.*, para. 22, lines 7-9.

Claim 8: wherein the elastomer has elasticity that is not constant or that is anisotropic. *See, e.g.*, para. 50, lines 4-8.

Claim 9: wherein the delivered size of the prosthesis can passively expand in at least one dimension over one day, in saline. *See, e.g.*, original Claim 9, para. 26, and para. 51.

Claim 10: passively expand at least 5%. *See, e.g.*, original Claim 9.

Claim 23: wherein the device is a non-articulating body devoid of endplates (Figures 1-8) made of a single solid elastomer (para. 23, para. 28, para. 46, para. 51, original Claims 4 and 23, Figures 1-7) with extensions for fixation to the adjacent vertebral bodies (original Claim 23, Figure 4, para. 40).

Claim 29: wherein the prosthesis has a body that is an oval or kidney shape for use as a total disc replacement (Figure 8, see para. 22 and 27 and the specification generally) spinal disc prosthesis that substantially corresponds to a shape of a human spinal disc and is devoid of endplates and allows motion between adjacent vertebrae (Figures 1-8, para. 22, lines 3-4), has exposed fibers on the cranial and caudal surfaces thereof, and wherein the body is a non-articulating solid monolithic cryogel body (*see* Figures 1-8, para. 23, para. 28, para. 46, para. 51 original Claims 4 and 23, Figures 1-7), having an ultimate compressive and tensile strength greater than about 1 MPa, an ultimate tensile stretch greater than about 15% (para. 24, para. 45) in at least one direction, and comprises extensions from the body for attachment to sides of a vertebrae (original Claim 29).

Claim 34: An implantable non-articulating total disc replacement spinal disc body having a superior surface and an inferior surface joined by a circumferential surface, the body defined by a solid (original Claim 4 and para. 23) biocompatible freeze-thaw hydrogel (para. 45, 46, 47, 50-51) with an ultimate strength in tension greater than about 100 kiloPascals that exhibits the flexibility to allow at least 2 degrees of rotation between the superior and inferior faces with torsions of at least 0.01 N-m without failing. (*see, e.g.*, original Claim 1).

Claim 35: wherein the implantable spinal disc superior and inferior surfaces are substantially that of a kidney (*see, e.g.*, Figures 1-8) corresponding to a human spinal intervertebral disc shape (Figures 1-8, para. 28, 37, 43), shaped and formed by an extended oval surface and an indented surface, and wherein the cross-section of the implantable spinal disc is substantially rectangular.

Claim 40: wherein the superior and inferior surfaces are covered with a surface treatment to promote attachment to adjacent vertebral bodies, and wherein the disc body is devoid of endplates (Figures 1-8) and consists essentially of a monolithic freeze-thaw polyvinyl alcohol (PVA) hydrogel (Figures 1-8, para. 23, 46, 51).

Claim 43: An implantable spinal total disc replacement body consisting essentially of a biocompatible solid polyvinyl alcohol (PVA) cryogel (Figures 1-8, para. 46, 47, 50, 51, 52) having an ultimate strength in tension greater than about 100 kiloPascals, the body having sufficient elasticity to allow for shock absorption and flexibility of motion between adjacent vertebrae (para. 22, lines 1-4 and 11-12) ...

Claim 46: wherein the device is a non-articulating body devoid of endplates (Figures 1-8).

Claim 47: wherein the device has a non-articulating passively expandable monolithic body of freeze-thaw cryogel that defines a core and annulus of the spinal disc implant (Figures 1-8, para. 46-56).

Claim 48: An implantable spinal total disc replacement having a flexible non-articulating solid body devoid of endplates (Figures 1-8), the body having a nucleus and

annulus that are both defined by a crystalline PVA hydrogel (para. 46-56), the body having a shape generally similar to that of a human spinal intervertebral disc (original Claim 1) with opposing top and bottom faces, wherein the crystalline PVA hydrogel has an ultimate tensile and compressive strength of at least about 100 kiloPascals (para. 24, original Claim 1) and exhibits sufficient flexibility to allow at least 2 degrees of rotation between the top and bottom faces with torsions of at least 0.01 N-m without failing (original Claim 1).

Claim 49: further comprising a fabric band attached to an axially extending circumferential surface of the body. (original Claims 24, 39, 45, Figure 4, para. 40, para. 54, para. 56).

Claim 50: wherein the band is molded to the axially extending circumferential surface of the body. (Figure 4, para. 48, para. 56, lines 16-18).

Claim 51: further comprising a porous (mesh, original Claim 16) material attached to superior (top) and inferior (bottom) surfaces of the body to allow for tissue ingrowth from adjacent vertebral tissue *in situ*. (Figures 4 and 5, para. 41, 52, 53 and 56 and original Claims 15, 16 and 40).

Claim 52: wherein the body is configured to passively axially expand *in situ* over time. (para. 26, original Claim 9).

Claim 53: wherein the body is configured to passively axially expand *in situ* between about 5% to about 600% over at least about 24 hours. (para. 51).

Claim 54: wherein the body is configured to expand in height *ex vivo* about 50% over about 24 hours when placed in a bath of Normal saline (para. 56, original Claim 10).

Claim 55: wherein the body has anisotropic elasticity (para. 50).

Claim 56: wherein the body is monolithic and has substantially the same durometer for locations proximate the nucleus and the annulus. (Figures 1-8, para. 46-56).

Claim 57: further comprising at least one inferior tab and at least one superior tab extending from the body (Figure 4, para. 40, original Claims 39 and 45).

Claim 58: wherein the body is configured to passively expand in a physical dimension (para. 26), and wherein the body further comprises a fabric moldably attached thereto (Figure 4, para. 56) with fabric appendages (para. 40, para. 56) extending outwardly from the body for attaching the disc to sides of target vertebrae (para. 40, 52, 55, 56, original Claim 15, Figure 4).

Claim 59: wherein the disc body has a fabric covering molded into the disc body to extend beyond the disc body to define fabric appendages used to affix the disc body to target vertebrae (para. 56, Figure 4).

Claim 60: wherein the body has an ultimate strength in tension and compression of a least 1 MPa (para. 46, lines 19-20) to thereby provide a relatively compliant body that has sufficient elasticity to allow flexible motion between vertebrae and act as a mechanical shock absorber (para. 22).

Claim 61: wherein the body has a mechanical ultimate tensile strength greater than 100 kiloPascals. (para. 24, para. 47, original Claim 1).

Claim 62: wherein the body can withstand 10 degrees of rotation between the top and bottom faces with torsions of greater than about 1 N-m (para. 46, lines 20-22).

Claim 63: A spinal total disc replacement prosthesis (Figures 1-8) having a solid body (para. 23) consisting essentially of a freeze-thaw PVA cryogel (para. 46-56) that defines a core and annulus, wherein the prosthesis is non-articulating (Figures 1-8) and has an ultimate tensile strength that is greater than about 100 kiloPascals (para. 24, 47, original Claim 1).

Claim 64: wherein the body is devoid of endplates (Figures 1-8) and exhibits sufficient flexibility to allow at least 2 degrees of rotation between top and bottom faces of the body without failing with torsions of at least about 0.01 N-m (original Claim 1).

Claim 65: wherein the body has an ultimate stretch in at least one direction of at least about 15% (para. 24. para. 45).

Claim 66: wherein the body is unbounded on upper and lower surfaces to allow for axial expansion when placed in a Normal saline solution for about 24 hours (para.

26, para. 51, para. 56).

Claim 67: wherein the body is configured to passively change size (para. 26) and can withstand at least about 2 degrees of rotation between the top and bottom faces with torsions of at least 0.1 N-m without failing (original Claim 1).

Claim 68: wherein the body has an ultimate tensile stretch greater than 25 % in one direction. (original Claim 29)

Claim 69: further comprising a fabric sleeve on an axially extending surface thereof. (para. 40, Figure 4, para. 53, para. 54, lines 9-11, para. 55, para. 56).

Claim 70: wherein the body has anisotropic elasticity. (para. 50).

Claim 71: further comprising a plurality of axially extending tabs of that are attached to the body and extend beyond upper and lower bounds of the body in the axial direction (Figure 4).

Claim 72: further comprising a porous fabric material disposed on at least one surface of the solid body. (original Claims 15, 16, Figure 4, para. 55, 56).

Claim 73: the fabric is molded to the solid body (Figure 4, para. 56), wherein, in position, the fabric is affixed to vertebral bone. (Figure 4, para. 56).

In view of the foregoing, Applicant respectfully submits that the claimed subject matter is sufficiently supported by the application and requests that the written description rejections be withdrawn.

IV. Supplemental IDS

Applicant is submitting a supplemental Information Disclosure Statement (IDS) with Form PTO 1449 listing an article entitled "Lumbar Disc Arthoplasty".

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted electronically to the U.S. Patent and Trademark Office on October 20, 2006.

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